



PATENT

DAC
[Signature]

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Donnelly, et al.

Serial No.: 09/835,694 Case No.: 18972PCA

Art Unit: 1636

Filed: April 16, 2001

Examiner:

Garvey, Tara L.

For: NUCLEIC ACID VACCINES AGAINST HUMAN
INFLUENZA VIRUS (As amended herein)

MAIL STOP: PETITION
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

CERTIFICATE OF MAILING UNDER 37 C.F.R. 1.8(a)

I HEREBY CERTIFY THAT THIS CORRESPONDENCE IS BEING
DEPOSITED WITH THE UNITED STATES POSTAL SERVICE AS
FIRST CLASS MAIL IN AN ENVELOPE ADDRESSED TO:

COMMISSIONER FOR PATENTS
P.O. BOX 1450
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MERCK & CO., INC.

BY:

[Signature]

DATE:

10 DECEMBER 2004

**PETITION UNDER 37 C.F.R. §1.78(a)(3) TO
ACCEPT AN UNINTENTIONALLY DELAYED
PRIORITY CLAIM
UNDER 35 U.S.C. § 120**

Sir:

This Petition is entered in response to the Office Action mailed 13 July 2004.

(1) Please charge the fee under 37 C.F.R. 1.17(t) to Deposit Account No. 13-2755 as a large entity.

(2) The delay between the date the claim was due under 37 C.F.R. § 1.78(a)(2)(ii) and the date of entry of this Petition and the Amendment filed on a even date herewith was unintentional.

12/14/2004 HALI11 00000014 132755 09835694

01 FC:1454 1370.00 DA

(3) The continuing date for the above-identified has been amended to read as follows:

-- This application is a continuation of U.S. application serial no. 08/461,268, filed June 5, 1995, now abandoned, which is a continuation-in-part of PCT international application no. PCT/US94/02751, filed March 14, 1994, from which a U. S. national phase application was entered May 25, 1995, designated as U.S. application serial no. 08/450,462, now abandoned; PCT international application no. PCT/US94/02751 being a continuation-in-part of U.S. application serial no. 08/089,985, filed on July 8, 1993, now abandoned, which is a continuation of U.S. application serial no. 08/461,268, filed March 18, 1993, now abandoned. --

REMARKS

The above identified application is a continuation of U.S. application serial no. 08/461,268, filed June 5, 1995, now abandoned. A priority claim to this earlier application was made on the data sheet filed concurrently with the above-identified application and a copy is attached as Exhibit A.

The '268 application contains the remainder of continuing data relied on by Applicants. Page 1 of the '268 application is attached as Exhibit B. The continuing data from the '268 application reads as follows:

This is a continuation-in-part of the U.S. National Phase of PCT/US94/02751. The U. S. national phase application was filed in the U. S. P. T. O. on May 25, 1995 and has been designated as U. S. S. N. _____ (Attorney Docket No. 18972PI). PCT application PCT/US94/02751 was filed in the PCT on March 14, 1994. PCT/US94/02751 is a continuation-in-part of U.S.S.N. 08/089,985, filed on July 8, 1993, now abandoned, which was a continuation of U.S.S.N. 08/032,383, filed on March 18, 1993, now abandoned.

Presumably, the Examiner takes the position that failure to designate the U.S. application serial number for the U.S. national phase of PCT/US94/02751 constitutes a break in continuing data for this series of applications (i.e. U.S. application serial no. 08/450,462, filed May 25, 1995).

Applicants respectfully disagree.

PCT international application PCT/US94/02751 is listed in the continuing data from the '268 application as being a continuation-in part of U.S. application serial no. 08/089,985, filed July 8, 1993. Applicants respectfully take the position that this information is adequate to properly denote continuity of the respective series of U.S. and/or international applications. Applicants respectfully note the following:

(1) PCT/US94/02751 was filed March 14, 1994, claiming priority to both U.S. application serial nos. 08/089,985 (July 8, 1993) and U.S. application serial no. 08/461,268 (March 18, 1993). A copy of the front page of WO 94/21797 is attached as Exhibit C. To this end, the deadline for entry into U.S. national phase prosecution was September 18, 1995.

(2) PCT/US94/02751 designated the U.S., as shown on the front page of WO 94/21797 (Exhibit C).

Therefore, Applicants respectfully take the position that listing of PCT/US94/02751 only, as opposed to listing of both the PCT international data and any related U.S. national phase filing data, is appropriate in view of the June 5, 1995 filing date of the '268 application (i.e., prior to the 30 month deadline of September 18, 1995 for entry into U.S. national phase prosecution). Applicants turn to 37 C.F.R. § 1.78 (a)(2)(i) for guidance, which states in part:

[C]opening nonprovisional applications or international applications designating the United States of America must contain or be amended to contain a reference to each such prior-filed application, identifying it by application number (consisting of the series code and serial number) or international application number and international filing date and indicating the relationship of the applications. (emphasis added).

Applicants take the position that the spirit of 37 C.F.R. § 1.78 (a)(2)(i) has been met by listing within the continuing data the PCT international application number, PCT international filing date, and the relationship of this applications to earlier filed applications. For clarity sake, the current continuing data has been amended to include reference to U.S. application serial no. 08/450,462. However, Applicants respectfully suggest that this information is additive and is arguably not required to comply with Rule 78 priority requirements, considering the pendency of PCT international application PCT/US94/02751 at the time of the June 5, 1995 filing date of the '268 application.

If entry of the data in question is deemed to be required, Applicants respectfully reiterate that exclusion of such data was unintentional and respectfully take the position that entry of this Petition cures any alleged defect in the chain of continuity.

Respectfully submitted,

Date: 10 DECEMBER 2004

By: J. Mark Hand
J Mark Hand
Reg. No. 36,545
Attorney for Applicant
Merck & Co., Inc.
P.O. Box 2000
Rahway, NJ 07065-0907
(732) 594-3905

09/335,694

EXHIBIT A

Pat. Case No.

18972PCA

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Assistant Commissioner for Patents
Washington, D.C. 20231

Prior Application:

Examiner K. Hauda

Art Unit 1632

Sir: This is a request for filing a ☒ Continuation ☐ Divisional

application, under 37 C.F.R. 1.53(b), of pending application Serial No. 08/461,268 filed on

June 5, 1995

of John J. Donnelly, Varavani J. Dwarki, Margaret A. Liu, Donna L. Montgomery, Suezanne E. Parker, and John W. Shiver

(DATE)

(INVENTOR)

for NUCLEIC ACID PHARMACEUTICALS INFLUENZA MATRIX

(TITLE OF INVENTION)

1. The enclosed comprises a copy of prior application Serial No. 08/461,268, as filed on

June 5, 1995. The entire disclosure of this prior application is hereby incorporated by reference.

2. The filing fee is calculated below:

CLAIMS AS FILED IN THE PRIOR APPLICATION, LESS ANY CLAIMS CANCELED BY AMENDMENT BELOW

FOR	NUMBER FILED			NUMBER EXTRA		RATE	FEE	
Total Claims	25	-	20	5	x	\$18	\$90	
Independent Claims	11	-	3	8	x	\$80	\$640	
*Multiple Dependent Claims					x	\$270		
Basic Fee (minimum amount required)							\$710	
* Add this fee if application contains any multiple dependent claims, regardless of number.							\$1,440	Total Fee

3. The Assistant Commissioner is hereby authorized to charge any fees which may be required or to credit any overpayment to Account No. 13-2755.

4. ☒ Amend the specification by inserting before the first line the sentence:-- This is a ☒ continuation, ☐ division of application Serial No. 08/461,268

filed June 5, 1995

5. ☐ Cancel in this application original claims:6. ☐ Preliminary amendment enclosed.7. ☐ Information Disclosure Statement/PTO-1449 enclosed.8a. ☐ Transfer the drawings from the prior application to this application and abandon said prior application as of the filing date accorded this application. A duplicate copy of this sheet is enclosed for filing in the prior application file.8b. ☐ New formal drawings are enclosed.9a. ☐ Priority of application Serial No. _____, filed _____,

in _____ is claimed under 35 U.S.C. 119.

(COUNTRY)

9b. ☐ The certified copy of the priority application has been filed in prior application Serial No. _____, filed _____.10. ☒ The prior application is assigned to Merck & Co., Inc. Rahway, New Jersey11. ☒ The undersigned attorney or agent has:a. ☐ Power in the prior application as originally filed.b. ☒ Associate power, copy enclosed.

Respectfully,


 By: J. Mark Hand

Attorney _____ for Applicant(s)

Registration No. 36,545

Telephone: (732) 594-3905

Address: Merck & Co., Inc.
Patent Department
P.O. Box 2000 - RY60-30
Rahway, N.J. 07065-0907

Date: April 16, 2001

EXPRESS MAIL CERTIFICATE

DATE OF DEPOSIT April 16, 2001

EXPRESS MAIL NO. EL523909305US

I HEREBY CERTIFY THAT THIS CORRESPONDENCE IS BEING DEPOSITED WITH THE UNITED STATES POSTAL SERVICE AS EXPRESS MAIL "POST OFFICE TO ADDRESSEE" ON THE ABOVE DATE IN AN ENVELOPE ADDRESSED TO ASSISTANT COMMISSIONER FOR PATENTS, WASHINGTON, D.C. 20231.

MAILED BY

G.B. Crowley

DATE

4/16/01

**PCT**WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁵ : C12N 15/44, A61K 48/00, 31/70		A1	(11) International Publication Number: WO 94/21797																																																
			(43) International Publication Date: 29 September 1994 (29.09.94)																																																
(21) International Application Number: PCT/US94/02751		Lane, Chalfont, PA 18914 (US). PARKER, Suezanne, E. [US/US]; 3646 Carmel Landing, San Diego, CA 92130 (US). SHIVER, John, W. [US/US]; 125 Beulah Road, Doylestown, PA 18901 (US). ULMER, Jeffrey, B. [CA/US]; 128 Dolly Circle, Chalfont, PA 18914 (US).																																																	
(22) International Filing Date: 14 March 1994 (14.03.94)																																																			
(30) Priority Data: 032,383 18 March 1993 (18.03.93) US 089,985 8 July 1993 (08.07.93) US		(74) Agent: BENCEN, Gerard, H.; 126 East Lincoln Avenue, Rahway, NJ 07065 (US).																																																	
(60) Parent Application or Grant (63) Related by Continuation US 089,985 (CIP) Filed on 8 July 1993 (08.07.93)		(81) Designated States: BB, BG, BR, BY, CN, CZ, FI, HU, KR, KZ, LK, LV, MG, MN, MW, NO, NZ, PL, RO, RU, SD, SI, SK, TT, UA, US, UZ, OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).																																																	
(71) Applicants (for all designated States except US): MERCK & CO., INC. [US/US]; 126 East Lincoln Avenue, Rahway, NJ 07065 (US). VICAL INCORPORATED [US/US]; Suite 100, 9373 Towne Centre Drive, San Diego, CA 92121 (US).		Published With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.																																																	
(72) Inventors; and (75) Inventors/Applicants (for US only): DONNELLY, John, J. [US/US]; 1505 Bierwood Road, Havertown, PA 19083 (US). DWARKI, Varavani, J. [IN/US]; Apartment N, 1175 Broadway, Alameda, CA 94501 (US). LIU, Margaret, A. [US/US]; 4 Cushman Road, Rosemont, PA 19190 (US). MONTGOMERY, Donna, L. [US/US]; 9 Hickory																																																			
(54) Title: NUCLEIC ACID PHARMACEUTICALS																																																			
<table border="1"> <caption>Survival Data from Graph</caption> <thead> <tr> <th>Day after Challenge</th> <th>NP DNA (% Survival)</th> <th>Control DNA (% Survival)</th> </tr> </thead> <tbody> <tr><td>0</td><td>100</td><td>100</td></tr> <tr><td>2</td><td>100</td><td>100</td></tr> <tr><td>4</td><td>100</td><td>100</td></tr> <tr><td>6</td><td>100</td><td>100</td></tr> <tr><td>8</td><td>100</td><td>70</td></tr> <tr><td>10</td><td>100</td><td>50</td></tr> <tr><td>12</td><td>100</td><td>40</td></tr> <tr><td>14</td><td>100</td><td>20</td></tr> <tr><td>16</td><td>100</td><td>10</td></tr> <tr><td>18</td><td>100</td><td>10</td></tr> <tr><td>20</td><td>100</td><td>10</td></tr> <tr><td>22</td><td>100</td><td>10</td></tr> <tr><td>24</td><td>100</td><td>10</td></tr> <tr><td>26</td><td>100</td><td>10</td></tr> <tr><td>28</td><td>100</td><td>10</td></tr> </tbody> </table>				Day after Challenge	NP DNA (% Survival)	Control DNA (% Survival)	0	100	100	2	100	100	4	100	100	6	100	100	8	100	70	10	100	50	12	100	40	14	100	20	16	100	10	18	100	10	20	100	10	22	100	10	24	100	10	26	100	10	28	100	10
Day after Challenge	NP DNA (% Survival)	Control DNA (% Survival)																																																	
0	100	100																																																	
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28	100	10																																																	
(57) Abstract DNA constructs encoding influenza virus gene products, capable of being expressed upon direct introduction, via injection or otherwise, into animal tissues, are novel prophylactic pharmaceuticals which can provide immune protection against infection by homologous and heterologous strains of influenza virus.																																																			



FEE TRANSMITTAL

Patent fees are subject to annual revision.

TOTAL AMOUNT OF PAYMENT

\$1,370

Complete if Known

Application Number	09/835,694
Filing Date	April 16, 2001
First Named Inventor	Donnelly et al.
Examiner Name	Tory A. McKelvey GARVEY, Tara C.
Group Art Unit	1636
Attorney Docket Number	18972PCA

METHOD OF PAYMENT

☒ Deposit Account

Deposit Account Number

13-2755

Deposit Account Name

Merck & Co., Inc.

The Director is authorized to:

☒ Charge fee(s) indicated below ☒ Credit any overpayments

☒ Charge any additional fee(s) during the pendency of this application

FEE CALCULATION

1. BASIC FILING FEE

Large Fee Code	Entity Fee (\$)	Fee Description	Fee Paid
1001	790	Utility filing fee	
1002	350	Design filing fee	
1004	790	Reissue filing fee	
1005	160	Provisional filing fee	

SUBTOTAL(1) \$0

2. EXTRA CLAIM FEES

	Extra	Fee from below	Fee Paid
Total Claims	20	0	0
Independent Claims	3	0	0
Multiple Dependent Claims		\$300	

**or number previously paid, if greater; For Reissues, see below

Large Fee Code	Entity Fee (\$)	Fee Description
1202	18	Claims in excess of 20
1201	88	Independent claims in excess of 3
1203	300	Multiple dependent claim, if not paid
1204	88	**Reissue independent claims over original patent
1205	18	**Reissue claims in excess of 20 and over original patent

SUBTOTAL(2) \$0

FEE CALCULATION (continued)

3. ADDITIONAL FEES

Large Fee Code	Entity Fee (\$)	Fee Description	Fee Paid
1051	130	Surcharge - late filing fee or oath	
1053	130	Non-English specification	
1812	2,520	For filing a request for <i>ex parte</i> reexamination	
1251	110	Extension for reply within first month	
1252	430	Extension for reply within second month	
1253	980	Extension for reply within third month	
1254	1,530	Extension for reply within fourth month	
1255	2,080	Extension for reply within fifth month	
1401	340	Notice of Appeal	
1402	340	Filing a brief in support of an appeal	
1403	300	Request for oral hearing	
1452	110	Petition to revive - unavoidable	
1453	1,370	Petition to revive - unintentional	
1501	1,370	Utility issue fee (or reissue)	
1502	490	Design issue fee	
1460	130	Petitions to the Commissioner	
1807	50	Processing fee under 37 CFR 1.17(q)	
1806	180	Submission of Information Disclosure Statement	
8021	40	Recording each patent assignment per property (times number of properties)	
1809	790	Filing a submission after final rejection (37 CFR 1.129(a))	
1810	790	For each additional invention to be examined (37 CFR 1.129(b))	
1801	790	Request for Continued Examination (RCE)	
Other fee (specify)	1454: Acceptance of an unintentionally delayed claim for priority		1,370
Other fee (specify)			
SUBTOTAL(3)			\$1,370

SUBMITTED BY

Complete (if applicable)

Typed or Printed Name	J. Mark Hand	Reg. Number	36,545
Signature		Deposit Account User ID	
Date	12/10/2004		

Application Number: 09/835,694
Filing Date: 04/16/2001
First Named Inventor: Donnelly et al.
Group Art Unit: 1636
Examiner Name: Tery A. McKelvey
Attorney Docket Number: 18972PCA



FIRST CLASS MAIL CERTIFICATE

I HEREBY CERTIFY THAT THIS CORRESPONDENCE IS BEING DEPOSITED WITH THE UNITED STATES POSTAL SERVICE AS FIRST CLASS MAIL IN AN ENVELOPE ADDRESSED TO: COMMISSIONER FOR PATENTS, P.O. BOX 1450, ALEXANDRIA, VIRGINIA 22313-1450, ON THE DATE APPEARING BELOW.

MERCK & CO., INC.

MAILED BY

J. Mathias

DATE

10 DECEMBER 2004